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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,872	03/24/2004	Mian Ying Wang	10209.476	6611

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,872	WANG ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/17/08 has been entered.

Claims 1-13 are pending in the application.

It is noted that *Morinda citrifolia* may be referred to herein as 'MC' or 'noni.'

Claims 12-13 remain withdrawn from examination on the merits, being elected without traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement of 4/6/06.

Claims 1-11 were examined on their merits with regard to the elected species of *Morinda citrifolia* leaf extract. It is noted that in the most recent amendment submitted by Applicants with the RCE on 6/17/08, Applicants have amended claim 1 to specifically

recite wherein the MC product is a leaf extract, and have further amended claim 2 to recite wherein the product further comprises an ingredient such as MC fruit juice.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No.11/668,035 ('035). Although the conflicting claims are not

identical, they are not patentably distinct from each other because the claims of '035 'make obvious' claims 1-11 in this application for the following reasons:

Claims 1-16 of '035 are directed toward a method for inhibiting Aromatase and Aromatase enzymes that function to convert androgens to estrogens comprising administration of an MC product (which can be MC dietary fiber – see claim 5 of '035) between about 0.01 and 100%, quercetin between about 0.1 and 10%, rutin between 0.1 and 10%. The claims of '035 do not specifically teach the ingestion administration as Instantly claimed (claims 3 and 10).

It is noted that claim 1 broadly recites an MC leaf extract. Limitations from the specification are not read into the claims. Absent any clear definition of MC leaf extract, this product is given its broadest interpretation within reason. It is deemed that an MC leaf extract can be directed toward MC dietary fiber, because dietary fiber (cellulose for example) can be extracted from MC leaf. Thus, claim 2 adding additional dietary fiber woudl amount to the same, yet in an added amount, of MC leaf extract (being the dietary fiber). Clearly, a method for inhibiting Aromatase and Aromatase enzymes that function to convert androgens to estrogens makes obvious a method for selectively inhibiting estrogen production and providing estrogenic effects in that, plainly stated by the preamble of claim 1 of '035 states that inhibition of aromatase enzymes will inhibit estrogen production (selectively, by enzyme inhibition); inhibition of estrogen production would necessarily provide estrogenic effects.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

Claims 1-11 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly (US 6,340, 703) in view of Chang et al. (US 2006/00996900 A1) in view of Davis (US 5,708,038) in view of Elkins, R. (1998) in view of Flockhart et al. (WO 9307901 A1) in view of Wang et al. (2002).

The teachings of Kelly, Chang et al., Davis, Elkins,R. and Flockhart et al. were discussed in previous Office actions. None of the references prescribed administration of an MC product such as MC juice.

Wang et al. (2002) reported many traditional uses of MC plants (see entire reference, especially pages 1-3). Wang et al. explained that MC juice had been used to treat menstrual difficulties (see specifically, page 2, last paragraph), and further disclosed that MC fruit contained rutin (see specifically, p. 3, fourth full paragraph).

As discussed in previous Office actions (e.g., see the final Office action of 8/9/07) Change et al. taught that rutin was a compound known to bind to the estrogen receptor ([0068]).

Thus, MC juice is another compound in Applicants claimed list of ingredients which comprises estrogenic compounds and was known to cause estrogenic effects (treatment of menstrual difficulties). As keenly pointed out in previous Office actions, combining ingredients which were all known to be estrogenic (or which have been recognized as containing estrogenic ingredients) is obvious. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301. The ordinary artisan would have had a reasonable expectation that the combination of claimed elements would result in a composition with additive estrogenic effects.

Initially, Applicants reiterate the Graham factual inquiries and reassert the 103(a) statute (pp. 5-6, Remarks). Applicants contend that the Examiner has not set forth a *prima facie* case of obviousness under the 103(a) statute in light of the Graham factual inquiries because Applicants assert that the cited prior art of record does not teach every limitation in the claimed invention (p. 6, Remarks). Applicants assert that "...a rejection under Section 103 cannot stand it if contains a mere statement that the

claimed invention would have been obvious without explicitly enumerating the necessary factual findings.

The Examiner has set forth a clear case of obviousness in this and prior Office actions. The Examiner has not simply indicated that it would have been obvious to combine the Instantly claimed ingredients; but rather, provided a keen rational for why the ordinary artisan would have found that combining the Instantly claimed ingredients would be useful. Specifically, all of the claimed ingredients were either known estrogenic compounds, or ingredients known to contain estrogenic compounds. Combining ingredients based upon their known, similar functions is obvious (*In re Kerkohoven*).

> However, the claimed invention involves ranges, which produce unexpected results. In particular the process for utilizing a leaf at higher concentrations administration of Morinda citrifolia leaf extract according to the claims of the present invention have produced unexpected estrogenic affects, when viewed against the background of prior art which teaches that administration of whole foodstuffs containing isoflavones have shown no consistent effect and that plant sterols have been estimated to be approximately 1/400 of that recorded for estradiol. (pp. 6-7, Remarks).

While Applicants' arguments in contention of an unexpected result was carefully considered, such contentions are deemed mere allegations absent any side-by-side comparison with beta-sitosterol, a compound already known in the art to be inherent in MC leaf and additionally known to possess estrogenic activity as disclosed by Elkins and Davis. Absent such verifiable proof, Applicant's assertions are unsubstantiated. It is additionally pointed out that in the event that Applicants do convincingly verify an unexpected result, the claims must be commensurate in scope with such results.

Applicants further contend that the claimed ranges of MC provide for an unexpected result, which obviates this outstanding rejection: "…administration of a leaf extract according to the claims of the present invention produced an estrogenic effect nearly ½ as potent as that as shown by estradiol. Accordingly, the inventive processing methods utilized, and administration of the claimed invention, have produced unexpected estrogenic effects when taken in view of the prior art" (p. 7, Remarks). Applicant has not explained how this data is unexpected. One would expect that MC leaf extract would have estrogenic effects based upon the fact that it contains at least the flavonoid glycoside known to be estrogenic. Further, it appears that Applicants are reading limitations which are not present in the claims. The claim is directed broadly toward '*Morinda citrifolia* leaf extract'. A *Morinda citrifolia* leaf extract is broad enough to read on beta-sitosterol, alone. To reiterate from previous Office actions, Elkins, R. (1998) disclosed that MC leaf contains beta-sitosterol (p. 8 of Elkins). Applicants have not defined the phrase *'Morinda citrifolia* leaf extract' in the Specification, and although Applicants use a specific type of extract, these limitations are not read into the claims. Considering that plant extracts are known to be in the forms of crude extracts, partially purified extracts and purified extracts containing one compound, coupled with the fact that MC leaf contains beta-sitosterol offers that the breadth of the claim may mean that a "*Morinda citrifolia* leaf extract' *is* beta-sitosterol. The term 'extract' is simply a product-by-process. The patentability of this type of

product is centered around the product, and not the method for making. Thus, because beta-sitosterol is *extractable* from MC leaf, the interpretation of the breadth of *'Morinda citrifolia* leaf extract' as being beta-sitosterol is not unreasonable. Applicants argue that Kelly state "'….[c]linical and other studies done to date in this area are highly equivocal…..other biologically active components'…Kelly indicates that producing a consistent estrogenic effect by administration of isolated biologically active compounds was beyond the reach of one skilled in the art, and that the interplay between various compounds was sufficiently complicated so as to obfuscate from one skilled in the art which combinations of compounds would effectively act to produce the desired estrogenic effects..." (p. 7, Remarks). However, reading on, Kelly states "Even when a positive clinical effect has been obtained, it has been with a mixture of a plurality of isoflavones, as well as a wide range of other unidentified dietary components and other biologically active components – it is known for example that other compounds present in legumes such as flavonoids (eg. quercetin, luteolin, kaempferol and lignans) also are estrogenic and it is also likely that among the other 700 or so isoflavanoids present in the Leguminosae family there are as yet unidentified isoflavonoids with estrogenic activity" (Col. 3, lines 31-38). Hence, it appears that Applicants have misinterpreted the teachings of Kelly because Applicants' arguments are respectfully out of context with the actual teachings of Kelly. Kelly is teaching that estrogenic effects of natural materials is unpredictable (as recited in the passage cited by Applicants); however, ***Kelly specifically points out that flavonoids such as***

quercetin are known estrogenic compounds. Hence, Applicants' arguments are not found convincing.

Applicants argue that Kelly does not disclose the amount of quercetin as Instantly claimed. As stated in previous Office actions, quercetin was a known effective variable as quercetin was a known estrogenic compound. Where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Adjusting the amounts of quercetin as Instantly claimed is deemed routine optimization of a result effective variable and it not deemed inventive absent evidence of an unexpected result.

Applicants argue that "Chang discloses only that rutin is a flavonoid glycoside comprised of quercetin and a sugar, rutinose, and that many beneficial heath effects of rutin have been demonstrated. Chang fails to disclose the claimed ranges of rutin and quercetin, and fails to teach the unexpected result that higher concentrations cause an inhibition of enzyme induction…Chang's disclosure certainly does not provide insight that would have allowed one skilled in the art to solve the problem posed by Kelly, that administration of biologically active components had failed to produced [*sic*] consistent desirable estrogenic effects (p. 8, Remarks).

First, Applicants' rational including Kelly is respectfully found to be without merit because Applicants have mischaracterized the teachings of Kelly as indicated *supra*. While Chang does not disclose the amounts of rutin and quercetin as Instantly claimed, it was keenly established in the previous Office action that the routine adjustment of amounts of known, effective ingredients to incorporate into neutraceutical/pharmaceutical preparations was considered *prima facie* obvious to the ordinary artisan at the time the invention was made. Applicant's arguments that Chang fails to teach "...the unexpected result that higher concentrations cause an inhibition of enzyme induction" is unsubstantiated " because first, Applicants have not shown that higher amounts of rutin or quercetin have an unexpected result over the rutin and quercetin of the prior art. Applicants' arguments in contention of an unexpected result on page 6 of the remarks are associated with *Morinda citrifolia* leaf extract, and not with amounts of quercetin or rutin which may provide for an unexpected result. Thus, there is no evidence of record to indicate that the claimed ranges of quercetin or rutin provide for any unexpected estrogenic activity. Also, it is reminded that A rejection under 35 U.S.C. ' 103 based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention. Ex parte Raychem Corp, 17 U.S.P.Q. 2d 1417. Thus, the ordinary artisan at the time the invention was made, with the aforementioned references before him/her would have been motivated to combine the Instantly claimed ingredients because they were all known to have estrogenic effects. Thus, the ordinary artisan would have had a reasonable, predictable degree of

success in producing the claimed invention; and further, with the prior knowledge that both quercetin and rutin were estrogenic, the adjustment of concentrations of each of rutin and quercetin in neutraceutical/pharmaceutical preparations would have been well within the purview of the ordinary artisan at the time the invention was made.. "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.

Applicants argue:

> Kelly's concern with equivocal results is compounded by Davis' assertion, that even when effective, plant sterols produce only a mild estrogenic effect. Davis discloses that estrogens have been isolated from a number of plant sources and that to date, only three sterols having mild estrogenic activity have been isolated. Importantly, Davis teaches that the estrogenic activity of plant sterols has been estimated to be approximately 1/400 of that recorded for estrodile. Accordingly, not only does Davis fail to disclose the claimed ranges of quercetin and rutin, and the unexpected result that higher concentrations cause inhibition of enzyme induction, but Davis additionally teaches away from the use of plant sterols in favor of estrodile, as the plants produce only a mild estrogenic effect, approximately 1/400 of that recorded for estrodile (p. 8, Remarks).

Again, Applicants' assertions concerning Kelly have respectfully been taken out of context. Furthermore, Applicants' arguments concerning Davis tend to be tangential to the teachings of Davis who specifically teaches that beta sitosterol possesses estrogenic activity. Again, Applicants' arguments pertaining to 'higher concentrations' only pertain to the amount of Morinda citrifolia leaf extract as disclosed in the specification, the specific extract not being explicitly claimed.

Therefore, while Davis discloses the advantageous use of estradiol over other plant sterols, it is clear that 'estradiol' is 'beta-estradiol', the same compound found in MC leaf. Further, as Applicants state, Davis does not specifically teach rutin or quercetin or any other specific plant sterols. Thus, Davis does not 'teach away' from the use of other plant sterols such as rutin or quercetin in any pharmaceutical preparation or their own preparation as asserted by Applicants on pp. 7-8 of the Remarks. On the contrary; Davis is merely reporting the advantageous effects of beta-sitosterol which is not deemed to negate any positive estrogenic effects innately possessed by quercetin or rutin which were already known in the art:

> **Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments**. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition **does not become patentable simply because it has been described as somewhat inferior to some other product for the same use**." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (See, MPEP § 2123, emphasis added)

Thus, Applicants' arguments pertaining to Davis 'teaching away' from the claimed invention are not accepted

Further, with regard to the arguments pertaining to Davis, Applicant is again imparting piecemeal analysis to the references; while the rejection is made in view of the

combination of the references. It is reiderated that an unexpected result has not been established as Applicants contend.

[If]… there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007.From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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